K000829

APR 13 2000

Date: March 13, 2000

510(k) SUMMARY

SUBMITTED BY:

Bradford M. Spring
Manager, Regulatory Affairs
Becton Dickinson and Company
7 Loveton Circle
Sparks, MD 21152-0999

NAME OF DEVICE:

Trade Name:	Gatifloxacin, 5 µg, BBL™ Sensi-Disc™
Common Name/Description:	Antimicrobial Susceptibility Test Discs
Classification Name:	Susceptibility Test Discs, Antimicrobial
PREDICATE DEVICE:	Other BBL™ Sensi-Disc™ such as Ciprofloxacin, 5 µg, BBL™ Sensi-Disc™

DEVICE DESCRIPTION:

INTENDED USE:

Antimicrobial Susceptibility Test Discs are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Gatifloxacin 5µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Gatifloxacin of a wide range of bacteria, as described under Indications for Use below. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer, Bristol-Myers Squibb, and received FDA approval under NDA Nos. 21-061 and 21-062.

510(k) SUMMARY

INDICATIONS FOR USE:

Use of Gatifloxacin, 5 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Gatifloxacin. Gatifloxacin has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the Bristol-Myers Squibb package insert for this antimicrobic.

Active *In Vitro* and in Clinical Infections Against:

Aerobic Gram-positive microorganisms
Staphylococcus aureus (methicillin-susceptible strains only)
Streptococcus pneumoniae (penicillin-susceptible strains)

Aerobic Gram-negative microorganisms
Escherichia coli
Haemophilus influenzae
Haemophilus parainfluenzae
Klebsiella pneumoniae
Moraxella catarrhalis
Neisseria gonorrhoeae
Proteus mirabilis

Active *In Vitro* Against:

Aerobic Gram-positive microorganisms
Staphylococcus saprophyticus
Streptococcus pneumoniae (penicillin-resistant strains)

Aerobic Gram-negative microorganisms
Acinetobacter lwoffii
Citrobacter koseri
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca
Morganella morganii
Proteus vulgaris

PRODUCT DESCRIPTION:

Gatifloxacin 5µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Gatifloxacin supplied by the manufacturer, Bristol-Myers Squibb. Each Gatifloxacin disc is clearly marked on both sides with the agent and content. Gatifloxacin discs are furnished in cartridges of 50 discs each. Gatifloxacin cartridges are packed as either a single cartridge in a single box, or in a package containing ten cartridges.

Agar diffusion methods employing dried filter paper discs impregnated with specific concentrations of antimicrobial agents were developed in the 1940's. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

510(k) SUMMARY

PRODUCT DESCRIPTION (continued)

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the National Committee for Clinical Laboratory Standards (NCCLS) and is periodically updated. The latest NCCLS documents are M2-A7 (1/00) and M100-S10 (1/00).

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus* species] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the discs are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The determination as to whether the organism in question is susceptible (S), intermediate (I), or resistant (R) to an antimicrobial agent is made by comparing zone sizes to those found in the respective organism tables of NCCLS Document M2-A7 ("Performance Standards for Antimicrobial Disk Susceptibility Tests - Seventh Edition, Approved Standard", 1/00) and of NCCLS Document M100-S10 ("Performance Standards for Antimicrobial Susceptibility Testing", Tenth Informational Supplement, 1/00).

PERFORMANCE DATA:

See Bristol-Myers Squibb drug insert on Susceptibility Tests - Diffusion Techniques for Gatifloxacin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 13 2000

Mr. Bradford M. Spring
Manager, Regulatory Affairs
Becton Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152-0999

Re: K000829
Trade Name: Gatifloxacin, 5µg, BBL™ Sensi-Disc™
Regulatory Class: II
Product Code: JTN
Dated: March 13, 2000
Received: March 14, 2000

Dear Mr. Spring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000829

Device Name: Gatifloxacin, 5 µg, BBL™ Sensi-Disc™

Indications for Use:

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Neisseria gonorrhoeae
Proteus mirabilis

Active *In Vitro* Against:

Aerobic Gram-positive microorganisms
Staphylococcus saprophyticus
Streptococcus pneumoniae (penicillin-resistant strains)

Aerobic Gram-negative microorganisms
Acinetobacter lwoffii
Citrobacter koseri
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca
Morganella morganii
Proteus vulgaris

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000829

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter Use _
Optional Format 1-2-96